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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,606	12/22/1999	HEINZ PETER VOLLMERS	PATWA-2	5150
21559 7590 01/29/2007 CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER HARRIS, ALANA M	
			ART UNIT 1643	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/469,606

Applicant(s)

VOLLMERS ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/16/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,42,43 and 45-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,42,43 and 45-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.


Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.


ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments and Amendments

1. Claims 1, 4, 42, 43 and 45-56 are pending.
Claims 1 and 50 have been amended.
Claims 1, 4, 42, 43 and 45-56 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

3. The rejection of claims 1 and 50 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' amendments to the claims.

Claim Rejections - 35 USC § 102

4. The rejection of claims 1 and 50 under 35 U.S.C. 102(b) as being anticipated by Karnauchow et al. (Journal of Virology 70(8): 5143-5152, August 1996) is withdrawn in light of Applicants' amendments to the claims.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

5. The rejection of claims 1, 4, 42, 43 and 45-56 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicants reiterate in the Remarks submitted October 16, 2006 beginning on page 7 the claimed invention complies with the written description requirement of 35 USC § 112, first paragraph. Applicants also recapitulate the Court's decision regarding *Enzo Biochem* initialing set forth in the Remarks of December 7, 2005 and *Capon v. Eshhar*. Applicants conclude arguments noting the primary structure of CD55 need not be reiterated, described, or reproduced and the *Capon* decision supports this. These points of view and arguments have been carefully considered but found unpersuasive.

Participants of the interview conducted September 12, 2006 discussed means to withdraw the instant rejection, but definitive resolution did not result. The Examiner's position on the instant matter has not changed. While there may be just one N-linked glycosylation site this information does not provide relevant identifying characteristics and details on the tumor-specific N-linked glycostructure listed in the claims. It remains unclear what the structure is of the tumor-specific N-linked glycostructure. Location of the single N-linked glycosylation site on CD55 is not the same as knowing the structure. In view of Applicants not being able to define, nor characterize the glycostructure, one of ordinary skill in the art is not clear on the variability that possibly exists within the genus of glycoproteins. For the reasons of record and the established analysis provided in previous Actions there is insufficient to support the generic claims as

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provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645 and the rejection is maintained.

Claim Rejections - 35 USC § 102

6. Claims 1, 4, 42, 43 and 45-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Vollmers et al. (Cancer 76(4): 550-558, August 15, 1995/ IDS reference submitted January 26, 2004), as evidenced by Hensel et al. (Cancer Research 59: 5299-5306, October 15, 1999/ IDS reference submitted January 4, 2002). Vollmers discloses a tumor cell line 23132 (stomach carcinoma), which is the same as that initially noted in claim 1, line 5, see page 553, Figure 2 and column 2, In vivo...section. This cell line inherently has a glycoprotein comprising the human amino acid primary structure of CD55 and a tumor-specific N-linked glycostructure and exhibits and possesses the same properties as that claimed. This disclosed cell line comprises the said structure and glycostructure with a relative molecular mass of approximately 82kDa as evidenced by Hensel. The 23132 cell extract isolated in Vollmers is the same as Hensel's and inherently contains the same glycoprotein of about 82kDa, see Vollmers page 552, Western Blots sections and Hensel, page 5300, first column, Purification...section.

Applicants are reminded of *Atlas Powder Co. V. IRECO, Inc* 51 USPQ2d 1943 (Fed. Cir. 1999). Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously

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unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient, which is inherently contained, in the prior art.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

20 January 2006